IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION

UNITED STATES OF AMERICA, ET AL., EX REL. REBECCA MILLER,	)	
Plaintiffs,	)	Case No. 1:15CV00017
v.	)	**OPINION AND ORDER**
RECKITT BENCKISER GROUP PLC, ET AL.,	)	JUDGE JAMES P. JONES
Defendants.	)	

Sarah M. Frazier, LAW OFFICE OF SARAH FRAZIER, PLLC, Houston, Texas, Charles H. Rabon, Jr., RABON LAW FIRM, PLLC, Charlotte, North Carolina, Doug Landau, ABRAMS LANDAU, LTD., Herndon, Virginia, and John P. Leader, THE LEADER LAW FIRM, Tucson, Arizona, for Plaintiffs; Mitch Lazris, Gejaa Gobena, and Emily M. Lyons, HOGEN LOVELLS US LLP, Washington, D.C., for Defendants.

The plaintiff and relator, Rebecca Miller, brings this *qui tam* action on behalf of the United States, the District of Columbia, the Commonwealth of Puerto Rico, and 29 states, alleging that the defendants violated, and conspired to violate, the False Claims Act (FCA), 31 U.S.C. §§ 3729–3733, and numerous FCA-related local statutes, by fraudulently reporting to the government the best price of a prescription drug subject to such reporting under 42 U.S.C. § 1396r-8, by violating the Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7b, and by retaliating against her.

Pharmaceutical manufacturers such as the defendants must report to the government the lowest price ("best price") that they sell Medicaid-covered

prescription drugs to ensure that state Medicaid agencies receive the same benefits other purchasers receive. Miller alleges that the defendants agreed to provide rebates for the drug Suboxone in exchange for a customer's continued preferential treatment of Suboxone on certain commercial drug formularies, rebates that would have set a new, reportable best price. However, to avoid triggering a new best price while also appeasing the customer's desire for high rebates and therefore ensuring continued Suboxone sales, the defendants structured its contracts so that it appeared that a portion of the commercial rebates were negotiated under Medicare because Medicare prices are excluded from best price reporting requirements. Thus, she claims, the rebates led to the defendants' submission of false best price data, which shortchanged state Medicaid agencies the price to which they were entitled. After she raised concerns about this so-called bundled sale, Miller says she was fired.

The defendants now move to dismiss the action. The motion has been fully briefed and is ripe for decision.[1] For the reasons set forth below, I will grant the defendants' Motion to Dismiss in part with leave to amend but otherwise deny it.

[1] I will dispense with oral argument because the facts and legal contentions are adequately presented in the materials before the court and argument would not significantly aid the decisional process.

I. BACKGROUND.

A. The FCA, the AKS, and Best Price Reporting Requirements.

I begin with a brief overview of the statutes and regulations at issue in this matter.

1. The FCA.

The FCA imposes civil liability for anyone who –

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> (C) conspire s to commit a violation of [the FCA];
>
> . . . .
>
> [or]
>
> (G) knowingly makes, uses or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government[.]

31 U.S.C. § 3729(a)(1). The law also provides relief for employees who are retaliated against because of "lawful acts done by the employee . . . in furtherance of an action under [the FCA] or other efforts to stop 1 or more violations of [the FCA]." § 3730(h)(1).

2. The AKS.

The AKS is a criminal statute that prohibits a person from knowingly and willfully soliciting, receiving, offering, or paying any remuneration — such as a kickback, bribe, or rebate — in return for purchasing any good or inducing any person to purchase a good for which payment may be made under a federal health care program. 42 U.S.C. § 1320a-7b(b)(1), (2). There is no private action under the AKS, *United States ex rel. Nicholson v. MedCom Carolinas, Inc.*, No. 1:17CV34, 2020 WL 1245374, at *4 (M.D.N.C. Mar. 16, 2020), but an AKS violation constitutes a false claim under the FCA. 42 U.S.C. § 1320a-7b(g); *see, e.g., United States ex rel. Banigan v. Organon USA Inc.*, No. 07-12153-RWZ, 2016 WL 10704126, *2 (D. Mass. Aug. 23, 2016).

3. Best Price Reporting.

Medicaid "authorizes federal financial assistance to States that choose to reimburse certain costs of medical treatment for needy persons." *Pharm. Rsch. & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 650 (2003). Under the program's rebate mechanism, codified at 42 U.S.C. § 1396r-8, a drug manufacturer must enter into a rebate agreement with the Secretary of Health and Human Services to have its drugs covered by Medicaid. 42 U.S.C. § 1396r-8(a)(1); *United States ex rel. Conrad v. Grifols Biologicals Inc.*, No. RDB 07-3176, 2010 WL 2733321, at *2 (D. Md. July 9, 2010). Pursuant to these agreements and the applicable statute, drug

manufacturers report certain data points, including their "best price" on certain drugs, to the Centers for Medicare and Medicaid Services (CMS) on a quarterly basis. 42 U.S.C. § 1396r-8(b)(3)(A)(i). This allows CMS to calculate the rebate owed to state Medicaid agencies for each drug. *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 114–15 (2011) ("The amount of the rebates depends on the manufacturer's 'average' and 'best' prices, as defined by legislation and regulation.").[2] The purpose of this mechanism is "to give Medicaid the benefit of the best price for which a manufacturer sells a prescription drug to any public or private purchaser." *United States ex rel. Streck v. Allergan, Inc.*, 894 F. Supp. 2d 584, 588 (E.D. Pa. 2012) (quoting H.R. Rep. No. 101-881, at 96 (1990), reprinted in 1990 U.S.C.C.A.N. 2017, 2108).

Best price is defined as "the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity." 42 U.S.C. § 1396r-8(c)(1)(C)(i). The definition is inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates. § 1396r-8(c)(1)(C)(ii)(I). However, certain prices are excluded from the best price definition,

[2] I have omitted internal quotation marks, citations, and alterations here and throughout this opinion, unless otherwise noted.

including prices that are negotiated under Medicare Part D prescription drug plans. § 1396r-8(c)(1)(C)(i)(VI).

B. Factual Background.

The following facts are drawn from the Complaint[3] and are assumed to be true for the purposes of this motion.

1. The Parties.

Miller sues four entities: (1) Reckitt Benckiser Group PLC and (2) Reckitt Benckiser Inc. n/k/a Reckitt Benckiser, LLC (collectively Reckitt Benckiser Defendants), as well as (3) Reckitt Benckiser Pharmaceuticals, Inc. n/k/a Indivior, Inc. and (4) Reckitt Benckiser Pharmaceutical Solutions, Inc. n/k/a Indivior Solutions, Inc. (collectively Indivior Defendants).

Until December 2014, the Reckitt Benckiser Defendants and the Indivior Defendants were part of a "unified worldwide business enterprise based in the United Kingdom." Compl. ¶ 18, ECF No. 133. The "Reckitt Benckiser parent entity," was mostly "a consumer products conglomerate." *Id.* A "wing of the company" was based in Virginia and manufactured and sold specialty pharmaceuticals, including the drug Suboxone. *Id.*

[3] The Complaint referred to herein means the Fifth Amended Complaint, ECF No. 133.

A demerger occurred in December 2014, and as a result, the Reckitt Benckiser parent company spun off the pharmaceuticals business under the name Indivior, PLC, which is nominally based in the United Kingdom, has North American headquarters located in North Chesterfield, Virginia. The Complaint states that this North American headquarters comprises the Indivior Defendants. "The Reckitt Benckiser Defendants are headquartered in the United Kingdom and its North American headquarters are located in Parsippany-Troy Hills, New Jersey." *Id.* All of the defendants "conduct business" in the Western District of Virginia. *Id.* ¶ 12.

Relator Miller is a former employee of Reckitt Benckiser Pharmaceuticals, Inc. n/k/a Indivior, Inc. (hereinafter referred to as RB Pharma). Miller was hired by RB Pharma to serve as a senior financial analyst in its North Chesterfield, Virginia, office in May 2012, a position she held until she was fired on July 2, 2014.

Shortly after being hired, Miller became responsible for keeping track of contractual rebates so that RB Pharma could report to CMS the best price granted by the company for its drug Suboxone. Miller's job was not to calculate the best price figures or to submit any reports to CMS. Rather, she advised a vendor as to how to identify the highest contractual rebates granted, and she confirmed the accuracy of those rebates to RB Pharma's Chief Financial Officer Ryan Preblick and Senior Government Pricing Contracts Analyst Lisa McNair (later Finance Manager and Manager for Contracting and Reimbursement). It was McNair who submitted

the pertinent rebate data to CMS. Nonetheless, because of her job duties, Miller was privy to certain internal conversations about best price and related contract negotiations.

2. Pharmacy Benefits Managers and the Suboxone Landscape.

RB Pharma, as Suboxone's manufacturer,[4] contracts with companies known as pharmacy benefits managers (PBMs), middlemen-type organizations that manage the health insurance benefits that insureds receive. This position makes PBMs powerful because they can shut drug manufacturers out of certain health plans. Thus, a PBM can often demand favorable pricing from a drug manufacturer in exchange for the PBM's inclusion or favorable treatment of the manufacturer's drug on the PBM's formularies. Favorable pricing comes in the form of rebates. PBMs adjudicate pharmacy claims, and the rebate process works as follows: "[S]torefront pharmacies buy the drug from the manufacturer or distributor, dispense the drug to patients on such plans, then submit a claim for reimbursement to the PBM, which

[4] The Complaint alleges that "Reckitt Benckiser" has manufactured Suboxone since 2002. Many times, the Complaint refers generally to "Reckitt Benckiser." At other times, it refers to "Indivior," or to RB Pharma. In doing so and as discussed further *infra*, it is unclear to which entity Miller is attributing certain conduct. Compl. ¶ 27, ECF No. 133. In the Complaint's introductory paragraphs, Miller states that the "Reckitt Benckiser Defendants *and/or* the Indivior Defendants," violated the FCA and AKS. *Id.* ¶¶ 1, 2 (emphasis added). However, Miller alleges she worked for one of the Indivior entities, RB Pharma, *id.* ¶¶ 3, 19, and the allegations of supposed wrongdoing seemingly only implicate RB Pharma employees. *Id.* ¶¶ 3, 48, 50, 56.

pays the claim out of funds associated with its contract with the insurer. Then [the PBM] receives a rebate on the back end from the manufacturer." *Id.* ¶ 5. PBMs can also run their own mail order pharmacies and specialty pharmacies, in which the PBMs purchase their own drugs from manufacturers and directly compete with the pharmacies for which they adjudicate claims.

Initially, Suboxone had few competitors. However, in February 2013, Suboxone lost its exclusivity in the market when manufacturers received approval to sell a generic buprenorphine/naloxone tablet. By the end of 2013, the large PBM Express Scripts, Inc. (Express Scripts) had announced that it intended to shut Suboxone film out in preference to the generic tablet on the plans it managed. The potential outcome was this: "If generics were more accessible or cheaper for patients in either the retail or the mail order sector, many would discontinue Suboxone." *Id.* ¶ 42.

Around the same time, several contracts with PBMs approached the time for renewal or amendment, including contracts with Express Scripts. One of these contracts was its so-called commercial contract, which covered the direct mail order and specialty purchases (considered retail sales), as well as the pharmacy rebates. The prices negotiated under this contract implicated best price reporting.[5] As

[5] The pharmacy rebates are exempt from best price reporting requirements, but the mail order and specialty prices are best-price reportable. All three types of transactions are allegedly grouped in the commercial contract and are subject to the same pricing.

discussed *supra*, best price reporting allows state Medicaid agencies to receive the benefit of the same rebates manufacturers provide in retail settings. At the time of the Express Scripts negotiations, the commercial price for another PBM was set to become the new best price setter with 33% rebates.

Another, separate but concurrent contract was the Medicare Part D contract. Prices negotiated under Medicare contracts do not implicate best price reporting requirements.

It is in this situation that Miller alleges the illegal conduct occurred.

3. Contract Negotiations with Express Scripts.

In the Spring of 2014, several discussions transpired regarding the Express Scripts contracts. These discussions are summarized below:

Meeting 1 (March 25, 2014). Miller met with several RB Pharma employees, including the President of RB Pharma, its Finance Director, Controller, Finance Manager for Government Contracts and Reimbursement, and Rebate Administrator, and RB Pharma's Director of PBM and ACA Strategy. Outside counsel also participated. Citing the presence of counsel, Miller does not describe the content of this meeting.

Meeting 2 (March 26, 2014). This meeting concerned how to structure rebates in the Express Scripts commercial contract. RB Pharma's then head of commercial contracts, Rob Philo, opined that the company should offer rebates in the low 30%

range for highly managed plans and in the high 20% range for the Managed Medicaid, and it could "throw in" rebates in the high 20s for Medicare Part D. *Id.* ¶ 52. Miller objected that "RB Pharma could not bundle commercial and Part D pricing — these must be separate conversations." *Id.* ¶ 53. RB Pharma President Richard Simkin responded that the company could not put such conversations in writing, but that he or someone would have to take Express Scripts to dinner and verbally promise high rebates on Medicare Part D to be put in writing after the commercial contract was signed. President Simkin told Philo and the Director of PBM and ACA Strategy, Keith Lockwood, that they would have to discuss further "offline." *Id.* Miller "understood Simkin's comments to mean that RB Pharma was planning to disguise larger commercial discounts to Express Scripts as Part D discounts so that RB Pharma would not have to trigger a new best price." *Id.* ¶ 54.

Meeting 3 (March 26, 2014). Ryan Preblick, RB Pharma's Controller, "warned Miller not to repeat anything that had been said in the previous meeting." *Id.* ¶ 57. Miller interpreted this as an admission of fraud and a threat of retaliation.

Meeting 4 (April 9, 2014). Miller visited Lockwood's office and inquired about the Express Scripts negotiations. Lockwood expressed his belief that RB Pharma should offer a 48% rebate on highly managed plans. Allegedly,

> RB Pharma had taken the position that the blended average rate needed to be 33% or less so as not to create a new best price. Express Scripts had responded that its people could tell RB Pharma how to structure the deal with rebates across commercial, Medicare Part D, and managed

> Medicaid, so as to not create a new best price on the commercial contract.

Id. ¶ 59.[6] Miller asked Lockwood, "Is that legal?" and Lockwood responded that it was. *Id.*

During this meeting, Lockwood showed Miller a spreadsheet that represented RB Pharma's sales and rebates applied to Express Scripts Medicare Part D plans, which is incorporated into the Complaint.[7] The spreadsheet showed that PDP plans accounted for 42% of Express Scripts Part D business. "Miller understood that PDP stands for Medicare Prescription Drug Plans not subject to Medicare Advantage." *Id.* ¶ 61. The spreadsheet also indicated that RB Pharma planned to sell Suboxone to Express Scripts at a 43% discount on those PDP plans, and a smaller discount on other Part D plans, producing an average rebate rate of 33.09% for Part D plans. This deepened Miller's suspicions. No other Part D contracts received a rebate that high. Because RB Pharma "did not get any value for paying such a high rebate for open access where the PBM exerted little formulary control . . . it was clear that [RB Pharma] and Express Scripts were using Part D as an illegal 'sweetener' — an illegal

[6] Miller does not allege who from RB Pharma had taken the position that the company needed a 33% blended rate or who from Express Scripts had offered help on how to structure the deal to avoid a new best price.

[7] Miller received a copy of the spreadsheet from Lockwood via email a couple weeks later on April 24 or 25. Because this spreadsheet is attached to and incorporated into the Complaint, I have considered it in deciding the defendants' Motion to Dismiss. *Zak v. Chelsea Therapeutics Int'l, Ltd.*, 780 F.3d 597, 606 (4th Cir. 2015).

kickback in exchange for which Express Scripts would recommend Suboxone on plans it controlled." *Id.* ¶ 62.[8]

Meeting 5 and Correspondence (May 28, 2014). Miller met with RB Pharma's Compliance Officer, Brandy C. Duso, to discuss her fears that "what Reckitt Benckiser was doing was illegal." *Id.* ¶ 64. Duso advised Miller to contact the company's then VP General Counsel. Miller did so to report "her concerns about contract negotiations and their best price implications." *Id.* ¶ 65.

Meetings 6 and 7 and Correspondence (May 29, 2014). Miller participated in several phone calls about the negotiations with outside counsel and an in-house paralegal. Miller met with in-house counsel because of her emails with the VP General Counsel the day before. The Complaint does not include details about these interactions. Miller and the in-house attorney then met with President Simkin.

All of the above-mentioned communications "reinforce[d] Miller's . . . belief" that RB Pharma planned to shift commercial price discounts to pricing in the Part D contract. *Id.* ¶ 69. "It was obvious to Miller that the contract changes Reckitt Benckiser adopted in its contrast with Express Scripts were an attempt to evade a lower best price while actually offering new and deeper rebates to Express Scripts." *Id.* ¶ 70. The 43% rebate on non-Advantage Medicare plans, plans over which

[8] Elsewhere in the Complaint, Miller alleges that Express Scripts has "no control over the formulary that applies to Medicare patients who are not enrolled in a Medicare Advantage plan." *Id.* ¶ 7.

Express Scripts exerts no formulary control, was eventually included in the Medicare contract which was signed months after Miller was terminated in July 2014, but was backdated to May 2014.

The new draft commercial contract was created in March 2014, was signed on May 29, 2014, and was set to become effective in the third quarter of 2014. Miller alleges that she refused to sign "a required Contract Approval Form giving her consent to the signing of the Express Scripts contract" because she "knew that the contract was tainted by the illegal rebate averaging scheme which was designed solely to benefit [RB Pharma] by avoiding 'breaking' best price, which would have required paying higher rebates to Government payors." *Id.* ¶ 102.

Miller was fired on July 2, 2014.

C. Procedural History.

Miller originally filed her *qui tam* Complaint in the District of Arizona in 2015. The case was transferred to this Court, and over the course of the last six years, Miller filed various iterations of the Complaint, although never because of a motion to dismiss. In 2018, the United States declined to intervene in the case.

In the fifth version of the complaint in question here, Miller alleges five counts under the FCA. In Count 1, Miller asserts that the Reckitt Benckiser Defendants, including RB Pharma, violated the FCA by manipulating and misreporting best price and/or by violating the AKS, § 1320a(b), which resulted in the defendants knowingly

causing to be presented false or fraudulent claims for Suboxone-related payment or approval. In Count 2, Miller contends that the Reckitt Benckiser Defendants entered into a conspiracy with Express Scripts for the purpose of defrauding the United States and the Medicaid States. In Count 3, Miller alleges that the Reckitt Benckiser Defendants knowingly caused to be made or used false records or statements for payment or approval by the United States and continue to do so. In Count 4, Miller contends that the Reckitt Benckiser Defendants knowingly made and continue to make false records or statements material to an obligation to pay or transmit money or property to the Government — a reverse false claim under the FCA. In Count 36, Miller brings a claim in her own name individually for retaliation prohibited by the FCA.

Counts 5 through 35 reincorporate the factual allegations underlying the federal claims, and Miller claims that such conduct violates state law false claims acts and taxpayer fraud acts, or in the case of Count 7, the District of Columbia False Claims Act and in the case of Count 35, the False Claims to Government of Puerto Rico Programs, Contracts, and Services Act.

The defendants have moved to dismiss the Complaint citing numerous grounds, including that the Complaint fails to satisfy Rules 8 and 9(b) of the Federal Rules of Civil Procedure, fails to allege underlying FCA and AKS violations, and fails to sufficiently allege each defendant's participation in the alleged acts. The

defendants further argue that all claims against Defendant Reckitt Benckiser Group PLC, should be dismissed for lack of personal jurisdiction and because it has not been properly served.

On July 21, 2022, this Court stayed the case in light of the Fourth Circuit's decision to rehear en banc a case involving issues presented by the Motion to Dismiss. But upon rehearing en banc, the previous panel opinions were vacated and the district court's judgment was affirmed by an equally divided court. *United States ex rel. Sheldon v. Allergan Sales, LLC*, 49 F.4th 873, 873 (4th Cir. 2022).[9]

The stay was thereafter continued pending the decision of the Supreme Court in the consolidated cases of *United States ex rel. Proctor v. Safeway, Inc.*, No. 22-111, and *United States ex rel. Schutte v. SuperValu Inc.*, No. 21-1326, in which the issue involved the legal standard for scienter under the FCA. The Supreme Court rendered its decision on June 1, 2023. *United States ex rel. Schutte v. SuperValu Inc.*, 143 S. Ct. 1391 (2023). The parties have filed briefs addressing the decision's impact on the Motion to Dismiss. Accordingly, the motion is ripe for decision.

[9] The Supreme Court has since vacated the judgment and remanded it to the court of appeals. *United States ex rel. Sheldon v. Allergan Sales, LLC.*, No. 22-593, 2023 WL 4278440 (U.S. June 30, 2023).

II. PERSONAL JURISDICTION AND SERVICE OF PROCESS AS TO DEFENDANT RECKITT BENCKISER GROUP PLC.

The defendants argue, in part, that the action should be dismissed against Reckitt Benckiser Group PLC under Federal Rule of Civil Procedure 12(b)(2) for lack of personal jurisdiction and Rule 12(b)(5) for ineffective service of process.[10] I agree.

"[A] plaintiff must establish personal jurisdiction by a preponderance of the evidence but need only make a prima facie showing." *UMG Recordings, Inc. v. Kurbanov*, 963 F.3d 344, 350 (4th Cir. 2020). To do so, a court considers the allegations and supporting evidence regarding the defendant's contacts with the forum in a light most favorable to the plaintiff. *Id.*

The FCA contains a broad jurisdictional provision that permits worldwide service, 31 U.S.C. § 3732(a), and therefore, personal jurisdiction hinges on constitutional limits, or "whether the defendants have minimum contacts with the United States as a whole." *United States ex rel. Thistlethwaite v. Dowty Woodville*

[10] In her latest filing, Miller contends that the defendants have waived these defenses by not properly raising them in the Motion to Dismiss. Resp. to Corrected Br. 11, ECF No. 152. While the motion itself lacks reference to 12(b)(2) and 12(b)(5), Mot. 1, ECF No. 90, the defendants expressly raised the defenses in the accompanying memorandum in support, which was incorporated by reference into the motion. "[T]his is not a situation in which the defendant has exhibited conduct, such as extensive participation in the discovery process or other aspects of the litigation, that would suggest waiver is appropriate." *Goldsborough v. Marriott Int'l, Inc.*, No. 3:18-cv-02502-SAL, 2020 WL 13470961, at *4 (D.S.C. Nov. 10, 2020). Accordingly, I find that the defendants have not waived the defenses.

Polymer, Ltd., 976 F. Supp. 207, 210 (S.D.N.Y. 1997). This requires a due process analysis under the Fifth Amendment, and "an examination of the extent to which the defendant availed himself of the privileges of American law and the extent to which he could reasonably anticipate being involved in litigation in the United States." *Boon Partners v. Advanced Fin. Concepts, Inc.*, 917 F. Supp. 392, 397 (E.D.N.C. 1996). "The focus on the defendant's relationship with the forum underlies the general-specific jurisdiction dichotomy." *Douglass ex rel. Douglass v. Nippon Yusen Kabushiki Kaisha*, 46 F.4th 226, 242 (5th Cir. 2022).

A proper challenge to personal jurisdiction is a question for the court, and the burden is on the plaintiff to ultimately prove grounds for jurisdiction. *Mylan Lab'ys, Inc. v. Akzo, N.V.*, 2 F.3d 56, 59–60 (4th Cir. 1993). The court has broad discretion to determine the procedure for resolving such a challenge, but it is often appropriate for courts to dispose of such motions "as a preliminary matter." *Grayson v. Anderson*, 816 F.3d 262, 268 (4th Cir. 2016). A court may decide the jurisdictional issue without an evidentiary hearing, and when doing so, a plaintiff only needs to establish a prima facie case of personal jurisdiction. *Mylan Lab'ys., Inc.*, 2 F.3d at 60. Accordingly, the court must "take the allegations and available evidence relating to personal jurisdiction in the light most favorable to the plaintiff." *Grayson* 816 F.3d at 268. However, courts need not credit conclusory allegations, and a plaintiff must base his claim for personal jurisdiction "on specific facts set forth in the

record." *Sonoco Prods. Co. v. ACE INA Ins.*, 877 F. Supp. 2d 398, 405 (D.S.C. 2012). I find that Miller has failed to make a prima facie showing that this Court should exercise jurisdiction over Reckitt Benckiser Group PLC. General jurisdiction requires that the company's contacts with the United States are such that it is essentially "at home" here. *Daimler AG v. Bauman*, 571 U.S. 117, 137 (2014). Typically, a corporation is at home in the place of its incorporation and where its principal place of business is located. *Id.* However, there may be "exceptional case[s]" in which a court may exercise general jurisdiction when "a corporation's operations in a forum other than its formal place of incorporation or principal place of business may be so substantial and of such a nature as to render the corporation at home." *Id.* at 139 n.19.

Reckitt Benckiser Group PLC is a United Kingdom-based company and there are no allegations or evidence suggesting that its principal place of business is in the United States. There is no doubt the company's contacts with the United States are significant. It has one of its headquarters in New Jersey, as is alleged in the Complaint. The company's website[11] indicates that one-third of its total global revenue comes from the United States. It has three research and development facilities and six manufacturing facilities in the United States. Reckitt U.S.

[11] The court takes judicial notice of the company's website pursuant to Federal Rule of Evidence 201.

Overview, https://perma.cc/TDQ6-MBH6 (captured Aug. 4, 2023). Nevertheless, there is no indication that the company's operations are managed in the United States. *Perkins v. Benguet Consol. Mining Co.*, 342 U.S. 437, 448 (1952) (finding a court could exercise jurisdiction over a foreign company whose president relocated to the state and ran operations from there). Nor is there any indication what, if any, high-level decision making takes place in the United States. Furthermore, of the over 40,000 employees, only 4,600 employees are in the United States, and it is unclear if these employees are actually employees of Reckitt Benckiser Group PLC or of separate subsidiary entities. Therefore, there is nothing to suggest that "the United States is [ ] the center of [Reckitt Benckiser Group PLC's] activities or a surrogate for [Reckitt Benckiser Group PLC's] place of incorporation or head office." *Douglass*, 46 F.4th at 243.

I also find that Miller has failed to establish that it would be appropriate to exercise specific jurisdiction over Reckitt Benckiser Group PLC. Miller's claims as pled arise out of RB Pharma's activities, and as described in more detail *infra*, it is unclear what connection or control, if any, the British parent entity had over Suboxone manufacturing or best price reporting. *Daimler AG*, 571 U.S. at 127 ("Adjudicatory authority of this order, in which the suit arises out of or relates to the defendant's contacts with the forum is today called specific jurisdiction."). Miller argues on brief that the company "owned the company that is now Indivior and

through that company manufactured and distributed the drug Suboxone." Resp. Opp'n Mot. Dismiss 45, ECF No. 115. However, the Complaint is devoid of any facts to show that RB Pharma's or any of the other named defendants' contacts should be imputed to Reckitt Benckiser Group PLC. *Saudi v. Northrop Grumman Corp.*, 427 F.3d 271, 276–77 (4th Cir. 2005). Although Miller alleges in a conclusory fashion that the defendants were part of a "unified worldwide business enterprise," Compl. ¶ 18, ECF No. 133, even drawing all reasonable inferences in favor of Miller, nothing suggests that the separate corporate form should be disregarded because the subsidiaries were alter egos or agents of the British parent company or vice versa. Accordingly, I find that Miller has not met her burden to show that this court has personal jurisdiction over Reckitt Benckiser Group PLC.

Furthermore, Miller has failed show that Reckitt Benckiser Group PLC was properly served, which is also necessary for the court to exercise jurisdiction over it. *Murphy Brothers, Inc. v. Michetti Pipe Stringing, Inc.*, 526 U.S. 344, 350 (1999). "Because the United Kingdom is a signatory to the Hague Convention with the United States, Plaintiff[] . . . w[as] required to comply with the Hague Convention's procedures and requirements as mandated by Federal Rule of Civil Procedure 4(f)(1)." *Brown-Thomas ex rel. Brown v. Hynie*, 367 F. Supp. 3d. 452, 463 (D.S.C. 2019). The Hague Convention "provides a variety of methods for international service." *Id.* For example, Article 10 of the Convention provides the freedom of

"any person interested in a judicial proceeding to effect service of judicial documents directly through the judicial officers, officials or other competent persons of the State of destination." Service Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters ("Hague Convention") art. 10, Nov. 15, 1965, 20 U.S.T. 361. Private process servers are competent persons to effect service pursuant to Article 10. *Brown-Thomas*, 367 F. Supp. 3d at 464–65.

The question here is "whether that service was properly executed by the server." *Id.* at 465. To make such determination, I must examine United Kingdom service rules. *Id.* United Kingdom Civil Procedure Rules 6.3 and 6.5 permit personal service on a company by leaving it with a person holding a "senior position." U.K. Civ. P. Rule 6.3(2), 6.5(3)(b), https://perma.cc/A82R-87C7 (captured Aug. 6, 2023). "Senior position" is defined as "a director, the treasurer, the secretary . . ., the chief executive, a manager or other officer . . . ." U.K. Civ. P. Rules, Practice Direction 6A, https://perma.cc/Y2LG-QXAT (captured Aug. 6, 2023).

Here, the Proof of Service (Proof) indicates that an individual named George Attfua accepted the service on behalf of the company. Aff. of Process Server, ECF No. 86.[12] The Proof does not indicate Attfua's position at Reckitt Benckiser Group

[12] It was the Fourth Amended Complaint and the summons for that version of the complaint that Mr. Attufua received. The Fourth Amended Complaint was the first version

PLC, and there are no other affidavits filed that identify his role at the company. Thus, I find that Miller has not met her burden to show service was properly executed on the British company.

Miller argues in part that even if service was technically imperfect, in light of the other circumstances, including the COVID-19 pandemic, the court should not require strict compliance with the service of process rules. I disagree. Although "mere technicalities should not stand in the way of consideration of a case on its merits," *Scott v. Md. State Dep't of Lab.*, 673 F. App'x 299, 304 (4th Cir. 2016) (unpublished), service upon some unidentified person "was more than a technical error." *C&SM Int'l v. Prettylittlething.com Ltd.*, No. CV 19-4046-CBM-KSx, 2019 WL 7882077, at *2 (C.D. Cal. Oct. 8, 2019). Although actual notice affects whether Rule 4 should be liberally construed, it is not the standard. *Robertson v. Dameron*, No. 7:22-CV-00086, 2023 WL 2760078, at *2 (W.D. Va. Mar. 31, 2023). "[T]he rules are there to be followed, and plain requirements for the means of effecting service of process may not be ignored." *Armco, Inc. v. Penrod-Stauffer Bldg. Sys, Inc.*, 733 F.2d 1087, 1089 (4th Cir. 1984). Miller could have served one of the company's senior officials at their home if the company's offices were closed due to the COVID-19 pandemic at the time she attempted to execute service in January

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of the Complaint ordered to be served upon the defendants because the earlier filings were under seal.

2021.[13] Alternatively, she could have requested an extension of time to serve the proper senior official. *Sparks v. Mamer*, 2:20-CV-00661-KJD-VCF, 2020 WL 5077732, at *2 (D. Nev. Aug. 27, 2020). All and all, Miller has failed to meet her burden to show service of process was valid. *Buzztime Ent., Inc. v. Sony Comput. Ent. Eur. Ltd.*, No. 08-CV-0122 W (LSP), 2008 WL 11337017, at *3 (S.D. Cal. July 10, 2008) (finding that service was insufficient in part because the person serviced did not hold a senior company position as defined by United Kingdom service of process rules). Therefore, I will dismiss the action against Reckitt Benckiser Group PLC with leave to serve the company within 60 days of the filing of a new Complaint if the other deficiencies described herein are cured.

III. Sufficiency of the Allegations.

I turn next to the defendants' motion to dismiss for failure to state a claim. Generally, a "complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). Further, "the tenet that a court must

[13] It does not appear that the company's offices were completely closed because of the pandemic if Attfua was there to accept service.

accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." *Id.* "While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations." *Id.* at 679. Although a complaint need not contain detailed factual allegations, it must contain "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555.

Federal Rule of Civil Procedure Rule 9(b) requires that in alleging fraud, "a party must state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). Claims brought under the FCA must comply with Rule 9(b). *Smith v. Clark/Smoot/Russell*, 796 F.3d 424, 432 (4th Cir. 2015). In fact, the Fourth Circuit has noted that the rule applies with "special force" to FCA claims. *United States ex rel. Grant v. United Airlines Inc.*, 912 F.3d 190, 197 (4th Cir. 2018).

"With respect to allegations of fraud, the circumstances required to be pled with particularity under Rule 9(b) are the time, place, and contents of the false representations, as wells as the identity of the person making the misrepresentation and what he obtained thereby." *United States ex rel. Radcliffe v. Purdue Pharma, L.P.*, No. 1:05CV00089, 2009 WL 161003, *1 (W.D. Va. Jan. 25, 2009). Fraudulent intent may be alleged generally. Fed. R. Civ. P. 9(b). A fraud claim likely survives Rule 9(b)'s heightened pleading standard if "the court is satisfied (1) that the defendant has been made aware of the particular circumstances for which [it] will

have to prepare a defense at trial, and (2) that plaintiff has substantial prediscovery evidence of those facts." *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 784 (4th Cir. 1999). "At a minimum, for an FCA relator to satisfy Rule 9(b), he must provide particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted; describing a mere opportunity for fraud will not suffice." *United States v. Omnicare, Inc.*, 903 F.3d 78, 91 (3d Cir. 2018). Lack of compliance with Rule 9(b) is treated as a failure to state a claim under Rule 12(b)(6). *United States ex rel. Taylor v. Boyko*, 39 F.4th 177, 189 (4th Cir. 2022).

A. Allegations against Reckitt Benckiser Group PLC and Reckitt Benckiser Inc.

In addition to the Complaint's flaws regarding jurisdiction and service of process as to Reckitt Benckiser Group PLC, the defendants also contend that the Complaint should be dismissed against both Reckitt Benckiser Defendants because the Complaint does not sufficiently allege conduct by either entity or their employees. I agree.

Rule 9(b) mandates that a plaintiff identify each defendant's participation in an alleged fraud. *Haley v. Corcoran*, 659 F. Supp. 2d 714, 721 (D. Md. 2009). "In FCA cases, the relator must show that the parent company 'is liable under a veil piercing or alter ego theory, or that it is directly liable for its own role in the submission of false claims.'" *United States ex rel. Lisitza v. Par Pharm. Cos.*, No.

06 C 06131, 2013 WL 870623, at *5 n.6 (N.D. Ill. Mar. 7, 2013) (quoting *United States ex rel. Hockett v. Columbia/HCA Healthcare Corp.*, 498 F. Supp. 2d 25, 60 (D.D.C. 2007)). Allegations of general corporate overlap are not enough to support that one entity controlled or directed another to participate in a fraudulent scheme. *Id.* at *5.

Here, Miller collectively refers to defendants Reckitt Benckiser Group PLC and Reckitt Benckiser, Inc. as the "Reckitt Benckiser Defendants," and defendants Reckitt Benckiser Pharmaceuticals, Inc. and Reckitt Benckiser Pharmaceutical Solutions, Inc. as the "Indivior Defendants" or "Indivior." Compl. at 2, ECF No. 133. She sometimes phrases her claims against the defendants generally, or vaguely against the "Reckitt Benckiser Defendants *and/or* the Indivior Defendants," *id.* ¶ 2 (emphasis added).

The Complaint includes no allegations about the role either Reckitt Benckiser defendant played in the Express Scripts negotiations. Nor does she allege she was employed by either entity or that any of the other individuals implicated were employed by either entity. Rather, Miller alleges that she was employed by "Reckitt Benckiser Pharmaceuticals, now known as Indivior, Inc," (RB Pharma) and that "*its* executives concocted the plan to violate the AKS and Medicaid best price laws." *Id.* ¶ 3 (emphasis added). Ryan Preblick and Lisa McNair, the individuals to whom Miller confirmed rebates, are identified as RB Pharma employees. *Id.* ¶ 48. Keith

Lockwood, the individual who took part in the internal negotiation strategy discussion and who sent Miller the Medicare Part D pricing spreadsheet, is described as RB Pharma's Director of PBM and ACA Strategy. Miller refers to Richard Simkin as the "RB Pharma President." *Id.* ¶ 47.

All in all, the Complaint is devoid of any allegations that identify participation of the Reckitt Benckiser Defendants in the purported fraud, and it fails to include any allegation that would suggest that the entities were or are alter egos of one another. *United States ex rel. Yu v. Grifols USA, LLC*, No. 1:17-CV-2226-GHW, 2021 WL 5827047, at *13 n.7 (S.D.N.Y. Dec. 8, 2021).

Nor does the Complaint indicate that Miller expressed concerns about the Express Scripts negotiations to employees of the Reckitt Benckiser Defendants or that employees from either entity participated in her termination so as to suggest that either entity plausibly retaliated against her.[14] All in all, the involvement of Reckitt Benckiser Group PLC and Reckitt Benckiser Inc. is undeterminable, and the Complaint does not suggest more than a mere possibility of misconduct on either entity's part. *United States v. Universal Health Servs., Inc.*, No. 1:07CV00054, 2010 WL 4323082, at *3 (W.D. Va. Oct. 31, 2010). Therefore, I also find that the

[14] As discussed *infra*, Rule 9(b) does not apply to FCA retaliation claims. However, because the Complaint lacks any facts implicating these other entities in Miller's termination, the Complaint fails to satisfy even Rule 8(a)'s less stringent pleading standard. I find the same regarding Miller's state law claims.

dismissal of all claims against defendants Reckitt Benckiser Group PLC and Reckitt Benckiser Inc. n/k/a/ Reckitt Benckiser, LLC is warranted pursuant to Federal Rule of Civil Procedure 12(b)(6).

B. Sufficiency of the Allegations against the Remaining Indivior Defendants.

1. Counts 1, 3, and 4: Presentment, False Records, and Reverse Claims.

To plead a claim under the FCA,

> a relator must plausibly allege four distinct elements: "(1) [ ] there was a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter [knowledge]; (3) that was material; and (4) that caused the government to pay out money or to forfeit moneys due (i.e., that involved a 'claim')."

United States ex rel. Rostholder v. Omnicare, Inc., 745 F.3d 694, 700 (4th Cir. 2014) (quoting *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 788 (4th Cir. 1999). The defendants argue that Miller has not established falsity or scienter. They also argue that Counts 1 and 3 fail because the Complaint does not allege that Indivior presented any claim to the government for reimbursement. I'll address each argument, starting with whether Miller has sufficiently alleged an illegal quid pro quo amounting to fraudulent conduct.

"False" and "fraudulent" are not defined in the FCA, but "it is a settled principle of interpretation that, absent other indication, Congress intends to incorporate the well-settled meaning of the common-law terms it uses." *Universal*

Health Servs., Inc. v. United States, 579 U.S. 176, 187 (2016). Thus, falsity encompasses express falsehoods, as well as omissions and misrepresentations amounting to half-truths. *Id.* at 187–89.

The alleged fraudulent conduct can be summarized as follows. Miller took part in internal RB Pharma meetings and was privy to internal documents purportedly showing that RB Pharma offered, and Express Scripts accepted, price concessions through rebates in a 2014 Medicare contract that constituted consideration for preferential treatment of Suboxone on formularies associated with the RB Pharma and Express Scripts commercial contract. Had these rebates been properly accounted for on the commercial contract, they would set a new best price, and RB Pharma would have reported the new best price to the federal government and would owe more money to state Medicaid agencies in the form of rebates. The best price data submitted to CMS by RB Pharma was inaccurate, which violated both the certification contained within its mandatory rebate agreement that it would comply with the governing drug rebate program, as well as its certifications associated with its best price data submissions. Thus, Miller's theory of liability is that the 2014 Express Scripts contracts resulted in the violation of Medicaid best price regulations and amounted to an illegal kickback under the AKS, which she argues constitutes fraudulent conduct under the FCA.

I must decide if Miller's theory is cognizable under the FCA and also if Miller has sufficiently pled it. I first find that exchange of Medicare Part D discounts for the purpose of obtaining or maintaining commercial business, along with the alleged certifications pertaining to best price data within the rebate agreement and that accompanied data submissions, can constitute false or fraudulent conduct under the FCA. I agree with the defendants' primary argument that best price regulations explicitly exclude prices negotiated under Medicare Part D. 42 C.F.R. § 447.505. I also agree that CMS guidance exists which permits simultaneous negotiations for commercial and Medicare prices. Medicare Program; Medicare Prescription Drug Benefit, 70 Fed. Reg. 4194-01, 4246 (Jan. 28, 2005). But Miller's contention is not that prices negotiated under Medicare plans should have been reported or that the simultaneous negotiations were illegal, but rather that they were undisclosed discounts cloaked under the Medicare exemption but were not actually negotiated under Medicare Part D. The reporting of such discounts would not penalize RB Pharma "indirectly for the discounts they offer by law under other Federal drug programs," *id.*, because they constituted rebates not actually offered under Medicare Part D. Rather, they were concessions allegedly offered and accepted in exchange for favorable commercial contract formulary placement, concessions that would have affected RB Pharma's reportable "lowest price available." 42 C.F.R. § 447.505.

Furthermore, Miller also hinges her falsity argument on the AKS, a violation of which constitutes a predicate under the FCA. *United States ex rel. Nicholson v. MedCom Carolinas, Inc.*, 42 F.4th 185, 194 (4th Cir. 2022). "Under the [AKS], it is illegal for any person to knowingly solicit or receive 'remuneration' in return for referring any 'good, facility, service, or item to someone that will be paid for, at least in part, by a Federal health care program." *Id.* Given the statute's breath, I find that hidden renumeration given in the form of a rebate, in exchange for placement on formularies associated with a best-price-reportable contract, for a drug that is reimbursable by federal health care programs, is encompassed by the AKS.

It is notable that disguised discounts that circumvent best price reporting is mentioned in agency guidance as something to be monitored by the health care community to avoid running afoul of the AKS. OIG Compliance Program Guidance for Pharm. Mfrs., 68 Fed. Reg. 23,731-01, 23,734 (May 5, 2003). Furthermore, "Congress intended that 'remuneration' under § 1320a-7b(b)(1) be interpreted broadly to reach all types of fraudulent financial arrangements that were paid for by federal healthcare programs, including Medicare and Medicaid. The focus of the remuneration element of the statute is that something of value was exchanged." *United States ex rel. Perri v. Novartis Pharms. Corp.*, No. 15-6547, 2019 WL 6880006, at *14 (D.N.J. Feb. 21, 2019) (finding that a relator sufficiently alleged that a previously unavailable discount amount was something of value and therefore

constitutes remuneration under the AKS). All in all, I recognize that this is not the typical kickback theory involving personal bribes or the billing of unperformed services. However, the theory's novelty does not render it non-cognizable. *Id.* at *8 n.9. I find that Miller's theory does constitute a plausible FCA violation, as she alleges that the inducement, in the form of rebates, was an undisclosed side deal not properly accounted for on the correct contract and that such inducement resulted inpatient access to Suboxone on Medicaid-paid plans and underpayment to state Medicaid agencies.

I turn next to whether Miller has sufficiently alleged facts supporting her theory of liability. That is, does the Complaint satisfy Rules 8(a) and 9(b), and has she plausibly alleged falsity, scienter, and that any claims for payment were submitted to the government to support her FCA presentment and false records claims?

The defendants contend in part that Miller's allegations are threadbare and relate only to internal negotiating strategies that do not "make fraud a necessary hypothesis." Defs.' Reply Supp. Mot. Dismiss 15, ECF No. 119. In essence, the defendants argue that Miller has failed to allege sufficient facts to show an exchange and inducement, which pertain to falsity. I disagree.

I find that the Complaint meets Rule 8's plausibility standard, as well as the higher Rule 9(b) standard by including the "who, what, when, where, and how" of

the alleged illegal inducement, which serves as the underpinning for the alleged fraud in the form of underreported data submissions to CMS affecting state Medicaid agencies. *Bakery & Confectionary Union & Indus. Int'l Pension Fund v. Just Born II, Inc.*, 888 F.3d 696, 705 (4th Cir. 2018). The who is RB Pharma and Express Scripts, including RB Pharma employees President Simkin, head of commercial contracts Philo, Finance Director Neary, Controller Preblick, Director of PBM and ACA Strategy Lockwood, as well as Lisa McNair, the RB Pharma employee who was responsible for the actual data submissions to the government. The what is the inducement in the form of rebates on the Medicare contract used, at least in part, as sweetener for the commercial contract, which led to underreported best price submissions. The where is RB Pharma's Midlothian, Virginia, office. Finally, the how is 2014 contract negotiations between two entities that had an interest in the inducement, Express Scripts in the form of high rebates and RB Pharma in the form of a need to keep Suboxone favored on Express Scripts formularies and a desire to keep from setting a new best price. I note that there are some details missing from the Complaint, such as who from Express Scripts was involved in the negotiations, whether the proposed dinner President Simkin mentioned in Meeting 2 actually occurred, and the specific dates and methods of communications with Express Scripts.

Nonetheless, I find that the allegations of inducement satisfy Rule 9(b) as to the falsity element. The alleged facts supporting the illegal inducement contrast sharply with those present in a case involving a similar, but inverted, theory of liability in which the district court found that a Complaint failed to satisfy the Rule 9(b) standard. *Perri*, 2019 WL 6880006, at *17. There, the allegations supporting the exchange were that there had been no commercial discount in place prior to the alleged illegal exchange, that PBM had threated to remove the drug at issue from both commercial and Part D formularies, and that relator and his PBM counterpart handled both commercial and Part D contracting functions. *Id.* at *2, 17–18. The court found that this merely amounted to an opportunity for fraud, which was not sufficient under Rule 9(b). The *Perri* court also emphasized the fact that the relator was directly involved in the negotiations and that the Complaint lacked specifics regarding matters the relator would have known from his own observations as the person responsible for handling such negotiations. *Id.* at 17.

Here, Miller took part in some of the internal discussions regarding the Express Scripts contracts, and she alleges details about those meetings that did not involve counsel, including dates, who participated, and the comments made. However, some of the missing facts, such as whether the dinner with Express Scripts occurred and who from Express Scripts participate in the negotiations, would be solely within other employees' knowledge, not Miller's, and unlike in *Perri*, Miller

was not the one responsible for negotiating the rebates. More importantly, Miller goes beyond alleging an opportunity for fraud by simply alleging that RB Pharma failed to maintain a firewall between commercial and Medicare Part D negotiations at a time when the PBM threatened to remove the drug from the relevant formulary. Rather, the Complaint includes the specific allegation that RB Pharma employee Keith Lockwood stated that Express Scripts sought high rebates in April 2014, that RB Pharma had taken the position that its rate should not exceed 33% to avoid setting a new best price, and importantly, that Express Scripts responded that it could structure the deal across the contracts so as to not create a new best price on the commercial contract. Miller then alleges that the rebates on the executed commercial contract were 33% and the rebates on the executed Medicare Part D contract for the non-Advantage line of business was 43%, and the average Part D rebate was 33%, which was "unusually high" and that "[n]o current Part D contracts were receiving such a high rebate." Compl. ¶ 62. In other words, Miller alleges that RB pharma sought a way to structure the rebates across its commercial and Medicare contracts so as not to create a new best price. Express Scripts, seeking high rebates, offered to structure the contracts in that way, and the contracts involving the mixed consideration (rebates) were actually executed, contracts that implicated patient access to Suboxone on Medicaid-paid plans.

The defendants also argue that the secret inducement theory makes little sense considering the PBM can exert some control over the Medicare Part D formularies and that Suboxone was at risk of losing its status across all Express Scripts' formularies. That very well may have been the case, but I find that assertion will come down to a matter of proof. In light of Miller's allegations regarding Express Scripts' actual offer to structure the rebates across contracts so as to not create a new best price, and the execution of those contracts with the alleged bundled consideration, I find that I cannot accept defendants' alternate explanation for the higher Medicare Part D rebates at this juncture.

The defendants also contend that Miller has failed to satisfy the FCA falsity element because she has not sufficiently alleged the predicate AKS scienter. I disagree. The AKS requires that the remuneration be offered, solicited, or received "knowingly and willfully." § 1320a-7b(b). Miller alleges that the RB Pharma employees who were involved in Express Scripts engaged in such conduct — the secret inducement and the subsequent underpayment of rebates — knowingly. Compl. ¶¶ 116, 117. Moreover, she alleges facts to back up this claimed intent as to the alleged kickback scheme: RB Pharma employees' discussions of the bundling of not just the commercial and Medicare Part D contract negotiations, but also the contracts' pricing, as well as Express Scripts offer to structure the rebates across the contracts so that RB Pharma would not have a new best price to report. Moreover,

Miller alleges that President Simkin stated that RB Pharma should not put the deal in writing and that he or someone else from RB Pharma would have to take Express Scripts to dinner to promise higher Medicare Part D rebates to be put in writing after the commercial contract was signed. Given these allegations and the fact that Rule 9(b) permits malice, intent, and knowledge to be alleged generally, I find that Miller has sufficiently alleged a plausible AKS violation. *United States ex rel. Lutz v. Berkeley Heartlab, Inc.*, 225 F. Supp. 3d 487, 498, 500 (D.S.C. 2016). All in all, I find that Miller has sufficiently alleged the existence of a quid pro quo — that the Indivior Defendants knowingly and willfully exchanged Medicare Part D discounts in the form of rebates to maintain business on Express Scripts commercial formularies.

Notably, sufficiently alleging an improper quid pro quo is not enough. "In order for a false statement to be actionable under the False Claims Act, it must be made as part of a false or fraudulent claim." *Taylor*, 39 F.4th at 195. The "central question in all False Claims Act cases is whether the defendant ever directly or indirectly presented a false or fraudulent claim to the government, resulting in a call upon the government fisc." *Id.* The defendants contend that Counts 1 and 3 must be dismissed because there is no allegation that these defendants presented any claims to the government for reimbursement. I agree.

Counts 1 and 3 of the Complaint invoke the FCA provisions deeming persons liable for "knowingly present[ing] or caus[ing] to be presented, a false of fraudulent claim" and "knowingly mak[ing], us[ing], or caus[ing] to be made or used a false record or statement material to a false or fraudulent claim." § 3729(a)(1)(A), (B). The FCA defines "claim" as "any request or demand . . . for money or property." § 3729(b)(2). In contrast, Count 4 invokes the FCA's reverse false claims provision, which creates liability for a person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." § 3729(a)(1)(G).

Miller acknowledges that "Indivior is correct that best price submissions do not constitute claims," but contends that "allegations of kickbacks allowing circumvention of best price reporting . . . have been approved multiple times." Resp. Opp'n Mot. Dismiss 32, ECF No. 115. Miller also argues that she sufficiently alleges as false claims not only best price reports, "but also claims made to pharmacies for Suboxone on behalf of beneficiaries under the Managed Medicaid and Part D plans at issue." *Id.* at 33. In her latest filings, Miller doubles down on this indirect claim theory, that RB Pharma caused others to submit false claims, arguing that the "demands for payment . . . are pharmacy reimbursement claims

stemming from the use of Suboxone by Medicaid enrollees in plans administered by Express Scripts, and Indivior caused these claims to be submitted by negotiating the contracts at issue, including via false statements and records." Resp. to Corrected Brief 6, ECF No. 152. In other words, because RB Pharma and then Indivior submitted rebates, that proves that Suboxone sales to Medicaid occurred, and therefore the company's "scheme *necessarily* led to the presentment of claims to the government for payment." *Id.* at 8–9.

Rule 9(b)'s particularity requirement does not allow a plaintiff to describe a private scheme in detail but then allege that "claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the Government." *United States ex. rel. Nathan v. Takeda Pharms. N. Am., Inc*., 707 F.3d 451, 457 (4th Cir. 2012). However, Rule 9(b) may also be satisfied in the absence of allegations of specific false claims if there are specific allegations that necessarily led to the plausible inference that false claims were presented to the government. *Id.*; *Grant*, 912 F.3d at 197.[15]

Miller argues that the latter theory is what occurred because of RB Pharma's conduct here. I agree that the payment of rebates, an after-the-fact discount, indicates that claims for payment were made to the government. The problem,

[15] There is some ambiguity as to whether relators are required to plead presentment as an element when alleging a § 3729(a)(1)(B) violation. *Taylor*, 39 F.4th at 195 n.12. Two recent Fourth Circuit cases suggest that presentment is an element of such claims. *Id.*

though, is that despite Miller's arguments on brief, the third-party submissions of claims for payment for Suboxone is not the theory she pled. The inference created by the allegations in the Complaint is not that the defendants caused pharmacies or some other entity or individual to submit kickback-tainted claims to the government. Rather, the Complaint alleges that presentment came in the form of "any and all *claims for payment* during this period *by Defendants* for Suboxone *from the federal government and/or the Medicaid States* under the Medicaid program were rendered false claims." Compl. ¶ 111, ECF No. 133 (emphasis added). Miller refers specifically to the rebates themselves as the claims the defendants presented or caused to be presented for payment from the government. *Id.* ¶¶ 115, 128. She herself concedes that her pleading as to presentment and false records claims is "not perfect." Resp. Opp'n Mot. Dismiss 34, ECF No. 115.

Given Rule 9(b)'s "stringent pleading standard" and the "quasi-criminal nature of FCA liability," *Grant*, 912 F.3d at 197, I find that Miller cannot use her briefs to amend her Complaint to allege that it was not the defendants who submitted claims for payment to the government and that it was not the rebates themselves that were claims. *Burgess v. Wehn*, No. TDC-18-2168, 2019 WL 4277402, at *3 (D. Md. Sept. 10, 2019) ("Briefs in opposition to a dispositive motion may not be used to amend a complaint or add new claims."); *cf. Grant*, 912 F.3d at 199 ("Rule 9(b)'s heightened pleading standard requires that plaintiffs connect the dots, even if

unsupported by precise documentation, between the alleged false claims and government payment.").[16] Accordingly, I will dismiss Counts 1 and 3 with leave to amend.

The defendants also assert that Miller has failed to adequately allege that RB Pharma acted with the requisite scienter. Under the FCA, one acts with the requisite scienter if they "(1) have actual knowledge of the falsity of the information; (2) act in deliberate ignorance of the truth or falsity of the information; or (3) act in reckless disregard of the truth or falsity of the information." *Taylor*, 39 F.4th at 197. The Supreme Court recently clarified that the FCA's scienter requirement tracks the common-law requirements for claims of fraud. *Schutte*, 143 S. Ct. at 1400.

Thus, actual knowledge "refers to whether a person is aware of information," or the falsity of the submitted claims, deliberate ignorance refers to persons who are aware of a substantial risk that their statements are false, but avoid taking steps to confirm the truth, and reckless disregard encompasses those who are "conscious of a substantial and unjustifiable risk that their claims are false, but submit the claims anyway." *Id.* at 1400–01. The Supreme Court held in *Schutte* that what matters is the defendant's knowledge and subjective beliefs when submitting the claim (or reverse claim), not what the defendant may have though after the submission, or

[16] The allegations about how the rebate process generally works and that pharmacies submit claims for reimbursement with PBMs, Compl. ¶¶ 5, 32, ECF No. 133, does not cure the Complaint's deficiencies.

what an objectively reasonable person may have known or believed. *Id.* at 1399, 1401. Thus, "FCA's scienter standards are plainly satisfied by a defendant's conscious belief that his claims are false." *Id.* at 1402. If such an allegation is sufficiently pled, there is no need to determine whether the defendant's reading of the statute was objectively unreasonable. *Id.*

In their initial brief, the defendants argued that Miller failed to plausibly allege FCA scienter because Indivior's reading of the applicable law was objectively reasonable. Specifically, the defendants point to the CMS guidance that there is no prohibition on simultaneous negotiations of commercial and Medicare Part D contracts. In their Reply, the defendants reassert that position, and they also argue that the Complaint fails to plausibly allege that "Indivior acted with 'actual knowledge' that it was acting wrongfully and contrary to law." Defs.' Reply Supp. Mot. Dismiss 14, ECF No. 119. Now, in light of the Supreme Court's holding in *Schutte*, the defendants argue that Miller "cannot allege that Indivior consciously disregarded a substantial and unjustifiable risk that its claims were false because the Medicaid Best Price statute, regulations, and guidance are unambiguous." Corrected Brief on Impact of the *SuperValu* Decision 4, ECF No. 149. In response, Miller contends that RB Pharma had actual knowledge of these false claims (reverse claims), that she has sufficiently pleaded facts showing that state of mind, and that

the defendants are improperly collapsing the falsity and scienter analysis by arguing that their interpretation of best price laws are correct.

Rule 9(b) permits malice, intent, and knowledge to be alleged generally. However, relators must still satisfy Rule 8 and include more than conclusory allegations pertaining to scienter. *Taylor*, 39 F.4th at 199. I find that Miller has satisfied this standard by plausibly alleging actual knowledge. Again, the Complaint includes allegations that create a plausible inference that RB Pharma had actual knowledge of its alleged false submissions resulting in underpaid rebates, It is alleged that RB Pharma President Simkin understood that the bundling of Medicare Part D and commercial contract pricing, not just the negotiations, needed to be discussed under the table, that Express Scripts offered to help structure the rebates across the contracts to avoid setting a new best price, that the contracts were actually executed, and that RB Pharma, and then Indivior, submitted best price reports to CMS based on these contracts from 2014 until 2018, which resulted in the alleged underpayment of rebates to Medicaid agencies. This amounts to a plausible allegation of actual knowledge.

I agree with Miller that the defendants are attempting to collapse falsity and scienter by now arguing that the applicable law is unambiguous, and that RB Pharma complied with it. I now hold that Miller's theory, if proven, does constitute a best price violation and illegal kickback. As the *Schutte* decision makes clear, even if it

were true that a reasonable person could read the guidance as permitting simultaneous negotiations and the regulations excluding Medicare Part D negated pricing from best price reporting requirements as permitting the alleged quid pro quo arrangement, it is RB Pharma's subjective knowledge at the time of its submission, not its post hoc rationalizations or an interpretation that is objectively reasonable, that matters. *Schutte*, 143 S. Ct. at 1404. "For scienter, it is enough if [the defendants] believed that their claims were not accurate." *Id.* Miller has sufficiently alleged that here.

2. Counts 2 and 36: FCA Conspiracy and Retaliation.

Miller also brings two other federal claims: FCA conspiracy and retaliation. The defendants argue that Miller's conspiracy claim fails because the Complaint fails to include facts that show a meeting of the minds. As for retaliation, they argue that Miller has failed to allege she engaged in any protected activity and that Indivior had no notice of any protected activity. I will address each claim in turn.

"To plead a claim for an FCA conspiracy, the relator must allege that the conspirators 'agreed that a false record or statement would have a material effect on the Government's decision to pay a false or fraudulent claim." *United States ex rel. Ahumada v. NISH*, 756 F.3d 268, 280 (4th Cir. 2014) (quoting *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 673 (2008)). To survive a motion to dismiss, the relator "must do more than simply show that the alleged conspirators

agreed to make a false record or statement; the relator must also show that the conspirators had the purpose of getting the false record or statement to bring about the Government's payment of a false or fraudulent claim." *Id.* at 282. The relator must also allege that each member of the conspiracy joined the agreement and one or more conspirators knowingly committed at least one overt act in furtherance of the conspiracy. *Pencheng Si v. Laogai Rsch. Found.*, 71 F. Supp. 3d 73, 89 (D.D.C. 2014).

Here, Miller does not allege who from Express Scripts stated that the company could help structure the rebates across the contracts. However, she does allege that Express Scripts and RB Pharma entered into the contracts at issue in 2014 and what each company sought to gain from the agreements that allegedly resulted in fraudulent submissions to the government — high rebates for Express Scripts and the avoidance of additional rebates to the government and formulary maintenance for RB Pharma.

Moreover, the defendants' challenge to the conspiracy charge is confined to the argument that the Complaint lacks a showing of a meeting of the minds. However, Miller's allegation that Express Scripts offered to structure the deal so that best price was not implicated undercuts the defendants' argument that there was no meeting of the minds to defraud the government. Rather, this fact, assumed true at this juncture, indicates that the parties executed the contracts at issue with the intent

to submit underreported best price data, or in Express Scripts' case, assist RB Pharma to do so in a way that also benefited itself. For this reason, I will deny the Motion to Dismiss as to the conspiracy charge (Count 2) against the remaining Indivior Defendants.

The defendants also challenge Miller's retaliation claim. To establish a prima facie case of FCA retaliation, it must be alleged that (1) the employee engaged in a protected activity; (2) the employer knew about the protected activity; and (3) the employer retaliated against the employee in response. *Carlson v. DynCorp Int'l LLC*, 657 F. App'x 168, 170 (4th Cir. 2016). Proving a violation of the FCA is not an element of an FCA retaliation claim. *Id.* at 174. Nor does Rule 9(b)'s heightened pleading standard apply to FCA retaliation claims. *Grant*, 912 F.3d at 200.

There are two categories of conduct that constitute protected activities under the FCA. First is activity that supports an FCA action. *Carlson*, 657 F. App'x at 170. This type of conduct invokes a "distinct possibility" standard, that is, the conduct "reasonably could lead to a viable FCA action, or when litigation is a reasonable possibility." *Id.* at 171.

The second type of protected activity is that which is part of an effort to stop an FCA violation. *Id.* at 170. This encompasses a much broader array of activity –— conduct in which efforts are motivated by an objectively reasonable belief that the employer is violating or will violate the FCA. *Grant*, 912 F.3d at 201. Under

this test, "while the plaintiff's actions need not lead to a viable FCA action as required under the distinct possibility standard, they must still have a nexus to an FCA violation." *Id.* at 202. Internal reporting of violations can constitute protected activity, but merely expressing concern about regulatory non-compliance is not enough. *Id.*; *Perri*, 2019 WL 6880006, *19.

The activities at issue here are as follows:

- On March 26, 2014, Miller objected that RB Pharma "could not bundle commercial and Part D pricing – these must be separate conversations." Compl. ¶ 53, ECF No. 133.
- On April 9, 2014, Miller asked Lockwood if it was legal to structure the deal with rebates across commercial, Medicare Part D, and managed Medicaid plans so as not to create a new best price.
- On May 28 and 29, Miller corresponded with outside counsel and in-house counsel to report her "concerns about contract negotiations and their best price implications." *Id.* ¶¶ 64–68. The details of these conversations are not included in the Complaint.

Although there are some facts missing from the alleged conversations involving corporate counsel, the specific allegations that are included in the Complaint constitute more than just general concerns of illegality. *United States ex rel. Branscome v. Blue Ridge Home Health Servs.*, Inc., No. 7:16cv00087, 2018 WL

1309734, at *5 (W.D. Va. Mar. 13, 2018). Miller alleges that she repeatedly expressed concerns not just about simultaneous negotiations, but about bundled pricing between the contracts and the potential best price implications.

Nonetheless, the defendants argue that the Complaint is inadequate in that it fails to adequately allege notice. Notice is viewed from the employer's perspective and "turns on whether the employer is aware of the employee's conduct." *United States ex rel. Parks v. Alpharma, Inc.*, 493 F. App'x 380, 388 (4th Cir. 2012) (unpublished). It requires that the employer be on notice that "litigation is a reasonable possibility." *Id.* I agree with the defendants that this is where Miller's Complaint fails. Although Miller adequately alleges that she raised specific concerns regarding best price implications before she was terminated, nothing in the Complaint suggests that any employee of the remaining Indivior defendants might have known of a potential FCA action. *Zahodnick v. Int'l Bus. Machs. Corp.*, 135 F.3d 911, 914 (4th Cir. 1997); *Branscome*, 2018 WL 1309734, at *6 (citing cases).

I also note that the Complaint indicates that some of the alleged retaliatory activity appears to have occurred before the Express Scripts negotiations. Miller alleges that one of her colleagues falsely sent an email from her computer and her unnamed superiors retaliated against her for mishandling accounts. Compl. ¶ 95, ECF No. 133. This appears to have occurred sometime shortly after January 2013. Furthermore, Miller allegedly received lower performance ratings in her 2013

performance review, also prior to the Express Scripts negotiations at issue. *Id.* ¶ 96. These allegations undercut the causal connection between Miller's termination and her expressed concerns regarding the 2014 Express Scripts negotiations.

For these reasons, I find that Miller's FCA retaliation claim (Count 36) must be dismissed.

3. Counts 5–35: Miller's State Law Claims.

Miller also asserts that the defendants have violated various state laws. The defendants argue that certain counts are subject to dismissal for specific reasons pertinent to those state's laws. They also maintain that all the state law claims are subject to dismissal for the same reasons they assert the federal claims must be dismissed.

Miller concedes that Count 28 (Maryland) is subject to dismissal because the state did not intervene, Count 34 (Wisconsin) is partially subject to dismissal as to damages that arose after July 14, 2015, and Count 35 (Puerto Rico) is partially subject to dismissal as to damages that arose before July 23, 2018. Consequently, I will dismiss Count 28 entirely with prejudice, as well as limit Counts 34 and 35 as they pertain to allegations and damages that arose after July 14, 2015, and before July 23, 2018, respectively.

The defendants also assert that Count 9 (Georgia) should be dismissed because Miller failed to allege that the attorney general approved the suit and cites

to one of the two Georgia laws under which Miller sues. Miller brings Count 9 under the Georgia False Medicaid Claims Act, Ga. Code Ann. §§ 49-4-168 through 49-4-168.6, and the Georgia Taxpayer Protection False Claims Act, Ga. Code Ann. §§ 23-3-120 through 23-3-127. The defendants are correct that Georgia Taxpayer Protection False Claims Act requires Georgia Attorney General approval. Ga. Code Ann. § 23-3-122(b)(1). Moreover, the statute also provides that if a civil action can be commenced pursuant to the False Medicaid Claims Act, the claimant should proceed under that statute. *Id.* § 23-3-127. Accordingly, I will dismiss Count 9 as it pertains to the Georgia Taxpayer Protection False Claims Act but allow Miller to proceed under the Georgia False Medicaid Claims Act to the extent described below.

The defendants also assert that Count 19 (New Mexico) should be dismissed because Miller has not alleged or shown that the New Mexico Department of Human Services determined that substantial evidence of a violation of state law has occurred. Again, Miller brings Count 19 under two state laws, the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §§ 27-14-1 through 27-14-15, and the New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. §§ 44-9-1 through 44-9-14. The defendants cite specifically to the Medicaid False Claims Act which requires service of a copy of the complaint on the state and requiring the state to make a written determination of whether there is substantial evidence of a violation. N.M. Stat. Ann. § 27-14-7(C). A motion to dismiss an original complaint is not the

appropriate time to resolve this issue under New Mexico law because New Mexico makes its determination after the filing of the complaint. *United States ex rel. Ellis v. CVS Health Corp.*, No. 16-1582, 2023 WL 3204015, at *9 (E.D. Pa. May 2, 2023). However, where a relator has filed an amended complaint and had the opportunity to allege whether New Mexico has made a substantial evidence determination, the claim is subject to dismissal. *United States ex rel. Cestra v. Cephalon, Inc.*, No. 14–1842, 2015 WL 3498761, at *14 (E.D. Pa. June 3, 2015). Here, the operative Complaint is the Fifth Amended Complaint. The case was unsealed in 2018, and Miller was directed to serve the Fourth Amended Complaint on the defendants as well as all court orders in the plaintiff states. Order 2, ECF No. 61. Thus, Miller has had an opportunity to determine and allege whether New Mexico has issued her a determination. Because she had not done so, I will grant the motion as to the New Mexico Medicaid False Claims Act with leave to amend if she wishes to proceed under that statute.

As for the remaining state laws, the defendants assert that the counts should be dismissed for the same reasons the federal claims should be dismissed. Because Miller has insufficiently pled allegations against the Reckitt Benckiser Defendants, I will also dismiss Miller's state law claims against those defendants. As for the remaining Indivior defendants, given the insufficient allegations regarding the presentment, false records, and retaliation counts, I will also dismiss the state law

claims against those defendants with regard to the presentment, false records, and retaliation counts, with leave to amend. *United States ex rel. Schneider ex rel Schneider v. J.P. Morgan Chase Bank*, N.A., 224 F. Supp. 3d 48, 61 (D.D.C . 2016). However, given that the defendants do not argue that the various state laws raised do not permit reverse false claims and conspiracy actions and my finding that Miller has sufficiently alleged facts supporting those counts, Miller's case may proceed pursuant to those counts under the various state laws she raises, except as otherwise indicated in this subsection.

IV.

For the foregoing reasons, it is **ORDERED** as follows:

1. The Order Staying Case, ECF 140, is VACATED and the stay is lifted;
2. Defendants' Notice of Request to Resolve the Pending Motion to Dismiss Without Oral Argument, ECF No. 138, is GRANTED, and Plaintiff-Relator Miller's Request for Oral Argument on Defendants' Motion to Dismiss, ECF No. 137, is DENIED;
3. Defendants' Motion to Dismiss Relator's Fifth Amended Complaint, ECF No. 90 is GRANTED IN PART and DENIED IN PART;
4. The Fifth Amended Complaint is DISMISSED in its entirety without prejudice as to Defendants Reckitt Benckiser Group PLC and Reckitt Benckiser Inc. n/k/a Reckitt Benckiser, LLC.

5. As for the remaining defendants, Count 1, Count 3, and Count 36 of the Fifth Amended Complaint are DISMISSED without prejudice. Count 28 is dismissed with prejudice. The claims underlying the remaining counts brought under state law are limited as described herein.

6. Plaintiff is granted leave to file a Sixth Amended Complaint if she can correct the deficiencies described herein, provided it is filed within 30 days of entry of this Opinion and Order; and

7. Plaintiff must properly serve Defendant Reckitt Benckiser Group PLC within 60 days of the filing of the Sixth Amended Complaint in the event it asserts claims against this defendant.

ENTER: October 17, 2023

/s/ JAMES P. JONES
Senior United States District Judge